REMARKS

In the Office Action of March 22, 2005, the Examiner commented that a reference to the prior application must be inserted as the first sentence of the specification or application or in the application data sheet.

It is submitted that the reference to the parent application was inserted in the amendment to the specification previously submitted and was also identified in the application data sheet. However, as the parent application has since issued and we now have a patent number to include, applicants now substitute a new sentence identifying the parent application, its issued patent number and the fact that it is included in its entirety by reference. It may be noted that the inclusion by reference is also found in the application data sheet.

The specification has also been amended to identify the adjuvant QUIL A™ capitalized as required under the rules.

The Examiner has objected to using abbreviations for the antigenic components of the claimed vaccine the first time they are written. With the present amendments it is believed that this objection is overcome.

Claims 1-8, 11, 15, 17-19, 22-26, 28-30, 33 and 40 stand rejected under 35 U.S.C. 102(b) for being anticipated by Roberts (WO 94/22476). Roberts is relied for teaching multicomponent clostridial vaccines using somponin adjuvants. It is also relied on for teaching that non-clostridial antigents may be added including Moraxella Bovis and Haemophilus somnus. It is also said to teach administering such vaccine compositions parenterally in amounts between 0.5 ml to 10 ml, more preferably 1 to 5 ml (page 8, lines 24-34).

With the present amendments the rejection over Roberts is respectfully traversed. On review, there is a general mention that "non-clostridial antigens may also be added to the vaccines to afford protection against a wide spectrum of diseases." (page 5, lines 11 and 12). Such antigens as recited in the presently amended claims are listed. As noted by the Examiner, doses of between 0.5 ml to 10 ml, as well as the preferred range of 1 to 5 ml are also mentioned.

It is respectfully submitted, however, that Roberts does not provide an enabling disclosure for the ordinary skilled practitioner to prepare vaccines as presently claimed. At the time, in spite of Roberts' comments, multivalent clostridial

vaccines were provided in 5 ml dosages. In fact, all of the examples provided by Roberts used 5 ml dosages. That was the conventional dosage at the time.

Applicants pioneered low dosage multivalent clostridial vaccines, and now multivalent clostridial vaccines with additional antigens, in the present case M.bovis, as well as the H.somnus combination claimed in the patent issued from the parent application. Producing effective low dose (2 ml) multivalent clostridial vaccines solved a major problem in the cattle industry, as the traditional 5 ml dosages resulted in injection site damage and spoiled meat. This need and the dramatic positive market response to applicants' 2 ml vaccines was demonstrated during the prosecution of applicants' parent application, USSN 08/412,676.

Although Roberts may have mentioned in the 1994 PCT publication that vaccine ranges may be as low as 0.1 ml, preferably 1-5 ml, at the time and until applicants provided them to the industry, 2 ml dosage clostridial combination vaccines as claimed in the patent issued from the parent application and in this present application as now amended were never known or used.

Roberts mentioned the problem with the local reactions, on page 2, lines 5-7. His solution was to use saponins as adjuvants to reduce such site reactions. Roberts practiced his invention, however, by administering the vaccine in 5 ml doses, as shown in the examples. Also, although theoretically suggested, Roberts did not in anyway demonstrate the multivalent clostridial combined with other antigens as claimed by applicants. Without that showing, it could not be presumed that interference between the antigens precluding an effective combination vaccine would not occur.

Although Roberts mentions the possibility of having multivalent clostridial vaccines combined with other antigens and mentions the possibility of having extremely low dose volumes of vaccines, what is enabled and described is only a multivalent clostridial vaccine administered in 5 ml doses. Not only did Roberts fail to practice the use of low dose volumes, he did not incorporate non-clostridials, even in his 5 ml dose volumes.

Submitted herewith is a copy of the Boehringer Ingelheim Animal Health, Inc. Distributor Policy and Terms, including a list of products, prices, and dosage size. It is dated effective January 17, 1994. Under clostridials, on the second page of the

list of products, one 7-way clostridial and four clostridial combination vaccine products are listed. Although ALPHA-7™ is in a 2 ml dose size, all the combinations are in 5 ml dose sizes. In particular, BAR-VAC®-7/PINKEYE, which is an M.bovis clostridial combination vaccine, is listed in a 5 ml dose size. Also submitted herewith are publications describing the cost to the industry of injection site lesions. The publications are *Beef Today*, March 1991, pages 18 and 19, *Calf News Cattle Feeder*, September 1992, pages 3 and 4, *FeedStuffs*, August 24, 1992, *Beef Today*, September 1992, page 22.

These publications report the problem of injection site lesions and the cost to the industry. They also report the introduction of the 2 ml combination clostridial vaccine and its importance to the industry. As soon as the 2 ml clostridial vaccine was available to the industry it quickly took over the market for multivalent clostridial vaccines. In spite of that, even in 1994, the same year the Roberts application was filed, a major supplier still used 5 ml doses for all combination cattle vaccines. This was the standard in the art at that time.

Claims 46 and 47 stand rejected under 35 U.S.C. 102(a) for being anticipated by Roberts, which is said to teach administering amounts of the subject vaccine composition to

bovine animals.

For the reasons set forth above, the rejection of claims 46 and 47 over Roberts is respectfully traversed. Theoretical mention of various ranges and various non-clostridial antigens did not provide an enabling disclosure. The industry continued to use 5 ml doses, as did Roberts, until the introduction of applicants' vaccines.

Claims 1-6, 11, 15, 17-19, 28-29, 33 and 40 stand rejected under 35 U.S.C. 103(a) for being obvious over Animal Pharm 203, page 28, taken in view of Vision Vaccines. Animal Pharm is relied on for teaching Sommu Shield +7, a combination of H.sommus with 6-way clostridial protection for cattle. Animal Pharm is said to not specifically recite the use of an adjuvant or dosage amount. Vision Vaccines is said to teach eight, seven and four way clostridial vaccines with a SPUR™ adjuvant and a 2 ml dose.

The rejection over the Animal Pharm taken with Vision Vaccines in view of the present amendments is respectfully traversed. It is not believed that these references taken together teach a multivalent clostridial with Moraxella Bovis combination vaccine, as now claimed.

Animal Pharm 203, page 28, 5/20/90, discloses that Grand Laboratories had received U.S.D.A. approval for a multicomponent vaccine comprised of at least seven clostridial antigens formulated with H.somnus. This vaccine was in a 5 ml dose volume for cattle only, and was discontinued in 1996 because of reactivity. Page 1019, from the Compendium of Veterinary Products 1995/1996, which is of record, describes this product. Accordingly, this reference does not suggest the present invention, which is 2 ml dose multivalent clostridial vaccine combination with Moraxella Bovis.

It is respectfully submitted that none of the cited references, taken alone or in combination, provide an enabling disclosure for the claimed multicomponent clostridial vaccine comprising an effective amount of Moraxella Bovis and an adjuvant in a low dose volume of about 2 ml or less. The success of a 6-way clostridial, M.bovis combination vaccine for providing effective protective immunity with a 2 ml dose volume could not have been predicted until applicants prepared and demonstrated their vaccines.

Claims 46 and 47 stand rejected under 35 U.S.C. 103(a) for being obvious over Animal Pharm in view of Vision Vaccines.

For the reason set forth above regarding this combination of references, it is believed that the methods recited in claims 46 and 47 are also not obvious in view of the art.

The present application stands rejected under the judicially created doctrine of double patenting over the patent issued from applicants' parent application, U.S. patent 6,743,430.

With the present amendments it is believed that this divisional application is distinguished by being a combination with M.bovis instead of H.somnus and is not overlapping with the parent case.

In view of the above it is believed that claims 1-3, 11, 15, 17-19, 40, 46 and 47 are in condition for allowance. Favorable action is solicited. Should the Examiner consider a conference would be helpful in advancing the prosecution of this application, she is invited to telephone applicants' attorney at the number below.

In the event any fees are required with this paper, please charge our Deposit Account No. 02-2334.

Respectfully submitted,

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